REMARKS

In this Amendment, claims 23, 32, 56, 59-61 and 64 have been amended. Claims 23-77 remain pending after entry of this Amendment. No new matter is introduced by this Amendment. Reconsideration and reexamination is respectfully requested.

The section numbers in parenthesis below correspond to the section numbers in the Office Action of January 25, 2007.

Rejection Under 35 U.S.C. §112

Claims 32, 59, and 60 were rejected under 35 U.S.C. §112, second paragraph, as reciting improper Markush-type language. Applicants have amended claims 32, 59, and 60 to comply with the proper Markush format under MPEP 2173.05(h). Removal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

(1)

Claims 23, 32, 54, 56, and 60 were rejected under 35 U.S.C. §102(e) as being anticipated by Ragheb et al. (US 6,299,604). Applicants traverse as Ragheb et al. fail to teach every limitation of these claims.

Of the rejected claims, only claims 23 and 56 are independent. Regarding claim 23, Ragheb et al. fail to teach the claimed limitation of:

> forming a first coating on the ***inner surface*** of the stent, the first coating including an ***angiogenic substance*** …; and
>
> forming a second coating on the ***outer surface*** of the stent, the second coating including a ***therapeutic substance capable of inhibiting migration or proliferation of smooth muscle cells***…

Regarding claim 56, Ragheb et al. fail to teach the claimed limitation of:

> applying a first composition to the ***inner surface*** of the stent, the first composition including a first therapeutic substance capable of ***facilitating angiogenesis***; and

> applying a second composition to the ***outer surface*** of the stent, the second composition including a second therapeutic substance, the second therapeutic substance capable of ***inhibiting migration or proliferation of smooth muscle cells***.

The Examiner states that, in Ragheb et al., "each surface of the stent structure will carry a different bioactive material" and that Ragheb et al. "teach a range of drugs, medicaments and materials may be employed as the coating materials (col. 8, line 7-8), such as (col. 9, line 34-36) angioenine, i.e. an angiogenic substance and (col. 14, line 47-48) antiproliferative agent such as pacitaxel, which is capable of inhibiting smooth muscle cells proliferation or migration." However, Ragheb et al. do not disclose placing an angiogenic substance on the inner surface and placing an antiproliferative agent on the outer surface. Applicants submit that Ragheb et al. fail to disclose the ***specific combination*** of the above-quoted elements of claims 23 and 56.

According to well established patent law, a prior art reference cannot be said to anticipate a specific combination of elements when the reference merely discloses a genus that embraces a large number of combinations. In particular, when a species, such as a particular combination of elements, is not named, but instead it is necessary to select portions of teachings within a reference and combine them, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated (see MPEP 2131.02, citing Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)). Here, the Examiner is selecting portions of teachings within Ragheb et al. However, the portions picked out by the Examiner are not sufficiently limited or well delineated to support a finding of anticipation.

Ragheb et al. clearly lacks the detail needed to conclude that it anticipates the particular combination of elements of independent claims 23 and 56. Ragheb et al. states that "one or more bioactive materials or drugs may be delivered … from the lumen surface of the stent, and a different treatment may be delivered on the vessel surface of the stent" (col. 8, lines 2-5). Ragheb et al. goes on to mention a virtual laundry list of bioactive materials (see col. 9, line 27 – col. 10, line 18). If each of the active agent classes mentioned by Ragheb et al. can independently be placed on either the outer surface or inner surface of a stent, then Ragheb et al. purportedly anticipate a vast number of stent coating permutations or species. However, use of a broad and general disclosure to anticipate a specific combination of claimed features is impermissible (see MPEP 2131.02, citing In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962) (holding that a generic chemical formula, without more, could not anticipate a specific chemical formula because the generic formula encompassed a vast number and perhaps even a infinite number of compounds)). Thus, it cannot be said that Ragheb et al. anticipate the specific combination of features claimed by Applicants.

Without the specific combination of features claimed by Applicants, a stent in Ragheb et al. cannot offer the advantages of the current invention. The specific combination of claimed features can produce a device that can stimulate or promote formation of one or more collateral vessels downstream of the device implantation site, while at the same time prevent migration or proliferation of smooth muscle cells at the implantation site. However, there is no disclosure in Ragheb et al. of a manufacturing method for a stent with this specific combination of capabilities.

Claims 32, 54, and 60 depend from claims 23 or 56 and are novel over Ragheb et al. for at least the reasons given above for claims 23 or 56.

(2)

Claims 23, 33, 34, 36, 37, 43, 45, 46, 49, 50, 55, 56, 58, and 59 were rejected under 35 U.S.C. §102(e) as being anticipated by Weber (US 6,517,888). However, Weber fails to teach every limitation of these claims.

Of the rejected claims, only claims 23 and 56 are independent. Regarding claim 23, Weber fails to teach the claimed limitation of:

> forming a first coating on the ***inner surface*** of the stent, the first coating including an ***angiogenic substance*** ...; and
> forming a second coating on the ***outer surface*** of the stent, the second coating including a ***therapeutic substance capable of inhibiting migration or proliferation of smooth muscle cells***...

Regarding claim 56, Weber fails to teach the claimed limitation of:

> applying a first composition to the ***inner surface*** of the stent, the first composition including a first therapeutic substance capable of ***facilitating angiogenesis***; and
>
> applying a second composition to the ***outer surface*** of the stent, the second composition including a second therapeutic substance, the second therapeutic substance capable of ***inhibiting migration or proliferation of smooth muscle cells***

The Examiner states that in Weber "the inner and outer surface of the stent can be coated with different materials." The Examiner then cites col. 2, lines 37-38 as disclosing "forming a first coating on the inner surface of the stent," cites col. 7, line 17 as disclosing "the first composition including a first therapeutic substance capable of angiogenesis," and cites col. 6, line 41 as disclosing "applying a second composition to the outer surface of the stent, the second therapeutic substance capable of inhibiting migration or proliferation of smooth muscle cells." However, Weber does not disclose placing an angiogenic substance on the inner surface and placing an antiproliferative agent on the outer surface. Further, the Examiner has selected portions of teachings within Weber that are not sufficiently limited or well delineated to support a finding of anticipation (see MPEP 2131.02, citing Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)).

Like Ragheb et al., Weber clearly lacks the detail needed to conclude that it anticipates the particular combination of elements of independent claims 23 and 56. Weber provides a list spanning almost two columns of biologically active materials that can be released from a device coating (see col. 5, line 57 – col. 7, line 23). Although Weber provides that the inner and outer surface of the medical device can be coated with different materials, Weber does not disclose the specific combination of elements claimed by Applicants. If each of the biological agent classes disclosed by Weber can independently be placed on either the outer surface or the inner surface of the stent, then Weber purportedly anticipates a vast number of stent coating permutations or species. Such a result is contrary to established patent law (see MPEP 2131.02, citing In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962) (holding that a generic chemical formula, without more, could not anticipate a specific chemical formula because the generic formula encompassed a vast number and perhaps even a infinite number of compounds)). Thus, it cannot be concluded that the very broad and general disclosure of Weber anticipates the specific combination of elements claimed by Applicants.

Claims 33, 34, 36, 37, 43, 45, 46, 49, 50, 55, 56, and 59 depend from claims 23 or 56 and are novel over Weber for at least the reasons given above for claims 23 or 56.

(3)

Claims 23-31 and 61-66 were rejected under 35 U.S.C. §102(b) as being anticipated by Loeffler (US 5,897,911). However, Loeffler fails to teach every limitation of these claims.

Of the rejected claims, only claims 23, 61, and 64 are independent. Regarding claim 23, Loeffler fails to teach the claimed limitation of:

> forming a first coating on the ***inner surface*** of the stent, the first coating including an ***angiogenic substance*** ...; and
> forming a second coating on the ***outer surface*** of the stent, the second coating including a ***therapeutic substance capable of inhibiting migration or proliferation of smooth muscle cells***...

As with Ragheb et al. and Weber, the Examiner has selected portions of teachings within Loeffler that are not sufficiently limited or well delineated to support a finding of anticipation (see MPEP 2131.02, citing Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)).

Loeffler clearly lacks the detail needed to conclude that it anticipates the particular combination of elements of claims 23 and 56. Loeffler provides a long list of therapeutic drugs, or agents that can be combined with the polymeric materials applied as coatings to a device (see col. 3, lines 4-32). If each of the biological agent classes disclosed by Loeffler can independently be placed on either the outer surface or the inner surface of a stent, then Loeffer purportedly anticipates a vast number of coating permutations on the inner and outer surface of a stent. However, the broad and general disclosure in Loeffler cannot be said to anticipate the specific combination of elements in claim 23 (see MPEP 2131.02, citing In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962) (holding that a generic chemical formula, without more, could not anticipate a specific chemical formula because the generic formula encompassed a vast number and perhaps even a infinite number of compounds)). Accordingly, claim 23 is novel over Loeffer.

Claims 24-31 depend from claim 23 and are novel over Loeffler for at least the reasons given above for claim 23.

Independent claim 61 has been amended to include the limitation "placing a removable cover ***on*** the outer surface of the stent." Loeffler fails to teach this limitation. The Examiner states that Loeffler teaches a method comprising "using a mandrel and/or mold, i.e. removable sheath to apply coating materials to the selected surfaces of the stent." However, Loeffler teaches that there is "spacing between … the exterior surface of the stent [19] and the interior of the external mold 21" (col. 4, lines 25-31; see also FIG. 2). As such, the mold is spaced apart from, not on, the exterior surface of the stent, which fails to meet the limitations of claim 23.

Independent claim 64 has been amended to include the limitation "temporarily placing a cover ***on*** the inner surface of the stent." Loeffler fails to teach this limitation. Loeffler teaches that there is "spacing between the exterior of the core pin [14] and the interior surface of the stent 19" (col. 4, lines 25-27; see also FIG. 2). As such, the core pin is spaced apart from, not on, the interior surface of the stent, which fails to meet the limitations of claim 30.

Claims 62, 63, 65, and 66 depend from claims 61 or 64 and are novel over Loeffler for at least the reasons as claims 61 or 64.

(4)

Claims 57 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Harish et al. (US 6,506,437). These claims depend from claims 23 or 56 and are patentable for at least the reasons given above for claims 23 or 56.

(5)

Claim 39 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Slaikeu et al. (US 6,663,607). This claim depends from claim 23 and is patentable for at least the reasons given above for claim 23.

(6)

Claims 42 and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Bowlin et al. (US 2002/0081732). These claims depend from claim 23 and are patentable for at least the reasons given above for claim 23.

(7)

Claims 51 and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Pierce et al. (US 2001/0044413). These claims depend from claim 23 and are patentable for at least the reasons given above for claim 23.

(8)

Claims 38 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Lane et al. (US 4,990,333). This claim depends from claim 23 and is patentable for at least the reasons given above for claim 23.

(9)

Claims 40 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Li et al., "PR39, A Peptide Regulator of Angiogenesis," Nature Med., Vol. 6, No. 1, p. 49 (January 2000). This claim depends from claim 23 and is patentable for at least the reasons given above for claim 23.

(10)

Claim 41 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Penta et al., "Del1 Induces Integrin Signaling and Angiogensis by Ligation of αβ3*," J. of Biological Chem., Vol. 274, No. 16, p. 1101 (April 1999). This claim depends from claim 23 and is patentable for at least the reasons given above for claim 23.

(11)

Claims 44, 47, and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in view of Kovesdi et al. (US 2003/0027751). These claims depend from claim 23 and are patentable for at least the reasons given above for claim 23.

Conclusion

Removal of the rejections and allowance of the application is hereby respectfully solicited. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9857.

Respectfully submitted,

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